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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/916,108 | 07/26/2001 | Allyson Beuhler | CM013991 (9640/73) | 7455 |

7590 09/17/2002
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EXAMINER

FORMAN, BETTY J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1634

DATE MAILED: 09/17/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/916,108

Applicant(s)

BEUHLER ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II, Claims 13-23, filed 8 July 2002 in Paper No. 7 is acknowledged.

Claims 1-12 have been cancelled as per Applicant's Amendment of Paper No. 7.

Claims 13-23 pending and are discussed below.

Priority

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The first paragraph of the specification recites "This application claims the benefit of co-pending U.S. Patent Application No. 09/612,792, filed July 10 2000". However, the recitation does not state the relationship between the instant application and the '792 application. Additionally, the Declaration does not claim priority to '792 application. As such, it is unclear whether Applicant is claiming priority to the '792 application.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 17 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 17 is indefinite for the recitation "the value corresponding to a number of biomolecules" because "corresponding" is a non-specific relational term and therefore the relationship between the value and the number is undefined. It is suggested that Claim 17 be amended to define the relationship e.g. replace "corresponding" with "identifying".

b. Claim 20 is indefinite for the recitation "quantitating element for correlating an amount of biomolecules" because "correlating" is a non-specific relational term and therefore the relationship between the quantitating element and the amount of biomolecules is undefined. It is suggested that Claim 20 be amended to define the relationship e.g. replace "correlating" with "determining".

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in-
 - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
 - (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in

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the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 13-16, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Stevenson et al (U.S. Patent No. 5,869,748, issued 9 February 1999).

Regarding Claim 13, Stevenson et al disclose a biosensor for assaying biomolecules comprising: a substrate having at least one biodetection site; and an electrical resonator proximate the biodetection site to allow measurement of magnetic properties at the biodetection site (Column 8, lines 47-60; Claims 1 and 16-18 and Fig. 4).

Regarding Claim 14, Stevenson et al disclose the biosensor wherein the detection site includes a holding substance i.e. a titer well comprising a disc coated with cell-binding substance (Column 9, lines 22-37).

Regarding Claim 15, Stevenson et al disclose the biosensor wherein at least one biochemical probe is present at the biodetection site (e.g. immunoglobulin, Column 9, lines 5-12).

Regarding Claim 16, Stevenson et al disclose the biosensor wherein the biodetection site is adapted to receive at least one biomolecule i.e. coated with cell-binding substance; and further comprising at least one magnetic tag operatively adapted to be applied to the biomolecule (Column 9, lines 22-37 and Claim 17).

Regarding Claim 18, Stevenson et al disclose the biosensor wherein the electrical resonator has a spiral geometry i.e. coil (Column 8, lines 51-58).

Regarding Claim 19, Stevenson et al disclose the biosensor comprising a measuring component for measuring the magnetic properties in communication with the biodetection site (Column 8, lines 53-55 and Claim 13).

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7. Claims 13-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Hawkins et al (U.S. Patent Application Publication No. 2001/0050555A1, filed 26 March 2001).

Regarding Claim 13, Hawkins et al disclose a biosensor for assaying biomolecules comprising: a substrate having at least one biodetection site; and an electrical resonator proximate the biodetection site to allow measurement of magnetic properties at the biodetection site (§ 0021-0029 and Claims 15-26).

Regarding Claim 14, Hawkins et al disclose the biosensor wherein the detection site includes a holding substance i.e. plastic film coated with rabbit anti-transferrin antibody for holding transferring (Fig. 13)).

Regarding Claim 15, Hawkins et al disclose the biosensor wherein at least one biochemical probe is present at the biodetection site (e.g. immunoglobulin, Fig. 13).

Regarding Claim 16, Hawkins et al disclose the biosensor wherein the biodetection site is adapted to receive at least one biomolecule i.e. transferrin; and further comprising at least one magnetic tag operatively adapted to be applied to the biomolecule (Fig. 13).

Regarding Claim 17, Hawkins et al disclose the biosensor wherein the electrical resonator measures a value of magnetic properties which correspond to a number of biomolecules at the detection site (§ 0128-0130 and Claim 14).

Regarding Claim 18, Hawkins et al disclose the biosensor wherein the electrical resonator has a spiral geometry i.e. coil (§ 0029 and Claim 21).

Regarding Claim 19, Hawkins et al disclose the biosensor comprising a measuring component for measuring the magnetic properties in communication with the biodetection site (§ 0026).

Regarding Claim 20, Hawkins et al disclose the biosensor further comprising at least one quantitating element for correlating an amount of biomolecules at the detection site to the magnetic properties of the biodetection site (§ 0026 and Claim 15-26).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevenson et al (U.S. Patent No. 5,869,748, issued 9 February 1999) in view of Kriz et al (U.S. Patent No. 6,110,660, issued 20 August 2000).

Regarding Claim 17, Stevenson et al teach a biosensor for assaying biomolecules comprising: a sample plate including a plurality of biodetection sites; a holding gel adapted to coat the biodetection site i.e. a cell-binding substance; and an electrical resonator operatively attached to the sample plate to allow measurement of magnetic properties at the biodetection sites wherein magnetic tags are applied to the biomolecule (Column 8, lines 47-60; Column 9, lines 5-37; Claims 1 and 16-18 and Fig. 4) but they do not specifically teach the resonator measures a value of magnetic properties. However, Kriz et al teach that measuring resonance from biomolecules attached to magnetic tags determines the amount of biomolecules present (Column 9, lines 6-16). Therefore, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to derive a value corresponding to the number of

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biomolecules from the magnetic measurement of Stevenson et al based of the teaching of Kriz et al wherein there is a direct correlation between magnetic measurement and number of biomolecules (Column 9, lines 6-16). One skilled in the art would have been motivated to derive the number of biomolecules for the obvious benefit of quantifying biomolecules in a sample to thereby accurately analyze the sample.

Regarding Claim 20, Stevenson et al teach the biosensor comprises an electrical resonator operatively attached to the sample plate to allow measurement of magnetic properties at the biodetection sites wherein magnetic tags are applied to the biomolecule (Column 8, lines 47-60; Column 9, lines 5-37; Claims 1 and 16-18 and Fig. 4) but they do not specifically teach the resonator measures correlates an amount of biomolecules at the site to magnetic properties of the site. However, Kriz et al teach that a resonator by measuring resonance from biomolecules attached to magnetic tags correlates an amount of biomolecules at the site to the magnetic properties of the site (Column 9, lines 6-16). Therefore, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to derive a value correlating to the amount of biomolecules at the site to the magnetic properties of the site using the biosensor of Stevenson et al based of the teaching of Kriz et al wherein there is a direct correlation between magnetic measurement and amount of biomolecules (Column 9, lines 6-16). One skilled in the art would have been motivated to derive the amount of biomolecules for the obvious benefit of quantifying biomolecules in a sample to thereby accurately analyze the sample.

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10. Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevenson et al (U.S. Patent No. 5,869,748, issued 9 February 1999) in view of Stratagene (catalog, 1988, page 39).

Regarding Claims 21-23, Stevenson et al teach a biosensor for assaying biomolecules comprising: a sample plate including a plurality of biodetection sites; a holding gel adapted to coat the biodetection site i.e. a cell-binding substance; and an electrical resonator operatively attached to the sample plate to allow measurement of magnetic properties at the biodetection sites (Claim 21); a solution of one biochemical probe adapted to be applied to the biodetection site i.e. cells (Claim 22); and solution of at least one magnetic tag adapted to be applied to the biomolecule (Claim 23) (Column 8, lines 47-60; Column 9, lines 5-37; Claims 1 and 16-18 and Fig. 4). Stevenson et al do not teach the sample plate, holding substance and electrical resonator combined into a kit. However, Stratagene catalog teaches a motivation to combine components into kit format (page 39).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the biosensor components of Stevenson et al into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. 2) The other service provided in a kit is quality control" (page 39, column 1).

11. Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hawkins et al (U.S. Patent Application Publication No. 2001/0050555A1, filed 26 March 2001) in view of Stratagene (catalog, 1988, page 39).

Regarding Claims 21-23, Hawkins et al teach a biosensor for assaying biomolecules comprising: a sample plate including a plurality of biodetection sites; a holding gel adapted to coat the biodetection site i.e. plastic film coated with rabbit anti-transferrin antibody; and an electrical resonator operatively attached to the sample plate to allow measurement of magnetic properties at the biodetection sites (Claim 21); a solution of one biochemical probe adapted to be applied to the biodetection site i.e. cells (Claim 22); and solution of at least one magnetic tag adapted to be applied to the biomolecule (Claim 23) (§ 0021-0029; ¶ 0128-130; Claims 15-26 and Fig 13). Hawkins et al do not teach the sample plate, holding substance and electrical resonator combined into a kit. However, Stratagene catalog teaches a motivation to combine components into kit format (page 39).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the biosensor components of Hawkins et al into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. 2) The other service provided in a kit is quality control" (page 39, column 1).

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this

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application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
September 13, 2002